

Serial No.: 10/803,148

REMARKS

Art Unit: 1614

Remarks

Reconsideration of the rejection of claims 1 and 14-15 of the present application under the judicially created doctrine of double patenting in view of U.S. Patent 6,702,733, U.S. Patent 6,322,493, U.S. Patent 6,223,541 and co-pending U.S. application serial no. 11/105,228, as well as the claim rejection under 35 USC 112, first paragraph, and 35 USC 103(a) over Thompson et al (5,425,954) in view of Kaplan et al., "Safety and Efficiency of Sildenafil in Postmenopausal Women with Sexual Dysfunction", Urology, Vol. 53, No.3, pp. 481-486 (Mar 1999), is hereby requested.

A Terminal Disclaimer, timely filed herewith, along with the proper fee, is believed to overcome the Examiner's rejection of the claims of the present invention under the above-cited co-owned U.S. Patents and Patent Application.

In the remaining independent claim 1, "comprised" has been replaced with "consisting of" to overcome the Examiner's concerns relative to anticipation of those claims.

Examiner rejects claims 1 and 14-15 under 35 USC 112 first paragraph as failing to comply with the written description requirement. Examiner states that the claims describe the function of the compound and not what the compound is.

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Independent claim 1 has however, been amended to recite that the compound *consists essentially* of: "L-arginine and a cooling agent *consisting of* Menthol and a 5-phosphodiaesterase inhibitor, wherein said combination contains menthol in a ratio of less than 10%, and said combination contains L-arginine in a ratio of less than 10%, and said combination also contains 5-phosphodiaesterase inhibitor in a ratio of less than 10%", (emphasis added). This is clearly a description of what the compound is, not what may be its function. There is clearly no undue experimentation necessary in following this formulation. The amount of each compound is identified and enables one skilled in the art to easily formulate same without any undue experimentation.

Examiner further rejects the claims under 35 USC 103(a) in view of the Thompson et al. '954 reference in view of the article of Kaplan et al. saying here that one skilled in the art "would have assumed" the combination of three individual agents well known to produce a cooling and sensitizing effect on various epidermal areas into a single composition. None of the components are suggested as a combination. This is hindsight construction. Absent any

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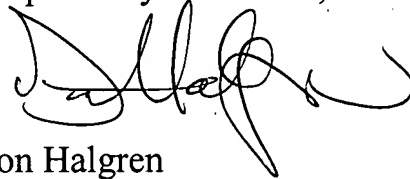
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teaching or suggestion of such a limited combination of components and percentages as recited in Applicants claims, the instant claims as amended should be allowed, such action being earnestly solicited,

If the Examiner believes that any issue remains unresolved, the Examiner is invited to call the undersigned for a discussion of same.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Don Halgren', written over a horizontal line.

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